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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rolf Muller

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EXAMINER

ANDERSON, JERRY W

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,835	Applicant(s) MULLER ET AL.	
	Examiner JERRY W. ANDERSON	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 6-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2,4 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Examiner acknowledges the receipt of the Applicant's Amendment, mailed 4/30/2009. Claims 1-2, 4, and 6-16, are pending, claims 1, 2, 6, and 7, amended, claims 11-16, new.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2, 4, 6-7, and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Y-C. Shi. (6,890,571)**

4. Regarding the limitations added by amendment, these are product by process claims; the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

5. Regarding Claim 1, the Applicant claims a slow digestible starch, partially gelatinized, with a DSC melting point is >60 deg C, and initial hydrolysis rate (Ho) is reduced by > 10 %, and 2-20% Short chain amylose, Shi teaches a resistant,

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gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571,) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours, (lines 5-14 col. 1 '571) the short chain amylase content is about 98 % (line 44-48 col. 3 '571) and is highly crystalline short chain amylose. (lines 46-28 col. 4 '571)

6. Regarding claim 2, Shi in '571 discloses the claimed invention, including hydrolysis rate being constant for at least 10 min, and less than 600 %/hr, as discussed below. The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of 15, 30, 45 and 60 minutes and calculating the digested portion of the starch. This data is plotted in Figures 1, 2, and 3. (pg 49 Applicant's specification) Shi measures the amount of glucose generated in the digestion reaction to give the digested portion of the starch at 20 min and 120 min. (lines 13-15 col. 7 '571) defines a rapidly digestible starch as being totally digested within 20 minutes. (lines 52-54 '571) Shi compares the amount of digested starch at 120 minutes with the amount at 20 minutes, to arrive at an estimate of the resistant starch. (lines 22-27 col. 7 '571) In the Applicant's data, Shi's rapidly digestible starch corresponds to Fig 1 Kellogg's corn flakes, and Fig. 3, Sample set WS-57 1-4. Applicant in Table 2 lists the Ho%/h for sample set WS-57-1 from 800 to 1000. Shi in Tables 1 and 2 lists the amount of starch digested at 20 minutes ranging from 20 to 50 % of the total starch, and 120 minutes from 50 to 70 % digested. (Table 1 '571) Shi's slowly digestible starch fraction, in Table 1 is about 24 %/120 minutes or about 14.5 percent per hour. Comparable with the

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Applicant's values of 30 per cent per hour, Sample KS-1 Table 2, Applicant. However, as per the Applicant's Figs, 1-3 the curve is non-linear versus time, and thus, Shi's results are lower than the Applicants for digestion per hour. Looking at the 20 min values for Shi, and comparing to the Applicant's 15 and 30 minute values, it can be seen that the results for both methods are overlapping. (Table 1 and 2, '571, Figs. 1 and 2 Applicant)

7. Regarding claim 4, Shi discloses the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 '571)

8. Regarding claims 6, 7, 11, 12, 13, 14, 15 and 16, are dependent upon claim 1, and detail the process by which the food stuff in claim 1 is prepared. As discussed above, Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours. (lines 5-14 col. 1 '571) Unless the claims listed herein add some patentably distinct characterization to the foodstuff, then said foodstuff is anticipated by Shi. ('571)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. Shi, (6,890,571) in view of Y-C. Shi. (5,593,503)**

12. These are product by process claims, the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

13. Regarding claims 8 and 9, '571 and '503 disclose the claimed invention, as discussed above, including food products, cereal, bread, crackers, cookies, pasta, coated and fried foods, made using said modified starch. (Lines 40-45 col. 4, Claim 27 '503)

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14. '571 and '503 are analogous art in the both are concerned with the modification of starches to form a starch that is resistant to digestion in humans.

15. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teachings of '571 and '503 in order to produce a food product that is likely to be a factor in the prevention of diverticulosis and colon cancer. (lines 30-32 col. 1 '503), and to produce a resistant starch that may contribute to reducing the risk of developing diabetes, or be useful in the treatment of hyperglycemia and obesity. (lines 36-40 '571)

16. Regarding claim 10, '571 and '503 disclose the claimed invention, as discussed above, including a discussion of increased organoleptic qualities such as crispiness, or preservative effects in those food products have good taste and appearance. (line 46, col. 9 '503, have acceptable mouthfeel and flavor, (line 67 col. 9, lines 30-31 col. 10, '503).

Response to Amendments

17. The applicant having cancelled claim 3, the 35 USC § 112 rejections thereunto is withdrawn.
18. The applicant having amended claim 7, the objection thereunto is withdrawn

Response to Arguments

19. Applicant's arguments filed 4/30/2009 have been fully considered but they are not persuasive.
20. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Furthermore, the burden shifts to applicant, who has chosen to describe his *product* by using physical characteristics that the Office has no resources to compare with prior art products by manufacturing the prior art product and making comparisons therewith. It is being assumed that since the reference has a similar product, made in a similar way, then the new feature being claimed must be present.

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21. It is well known that crystallization of starch produces a form of starch that is resistant to digestion, (Example 1, lines 43-67, col. 6, table 1, '503) Having formed a crystallite using the short chain amylose, which forms a resistant starch, that can be dried, ground and used in foodstuffs, (lines 20-51, col. 9, '571), it is obvious to one of ordinary skill in the art that further mixing of the short chain amylose, with a native starch, following by crystallization, would, likewise, produce a resistant starch.

Resistance to digestion is an inherent quality of crystallized starches. While the applicant has investigated and determined ranges and parameters optimal for the formation of starch crystallites, Shi, has, likewise, determined conditions conducive to the formation of similar resistant starches. (Table1, Table 2, and Table 3, '503)

22. One of ordinary skill in the art would have considered the invention to have been obvious because the parameters for the formation of the resistant starches of the prior art overlap the instantly claimed parameters and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the range disclosed in the prior art reference, particularly in view of the fact that: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" In re Peterson, 65 USPW2d 1379 (CAFC 2003)

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1794

Jwa